REMARKS

This Amendment is submitted in response to the Decision on Appeal mailed on August 24, 2010. A petition for revival of the above-identified application is submitted herewith. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712161-44 on the account statement.

Claims 1, 3-11, 13-16 and 18-22 are rejected in this application. Claims 2, 12, 17 and 23-25 were previously canceled without prejudice or disclaimer. In the Decision, Claims 1, 3-11, 13-16 and 18-22 are rejected under 35 U.S.C. §103. In response Claims 1 and 14-16 have been amended, and Claims 5, 7-8, 20 and 22 have been canceled. The amendments do not add new matter. In view of the amendments and/or for the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Decision, Claims 1, 3-11 and 13 are rejected under 35 U.S.C. §103(a) as being unpatentable over the publication to Di Marzo ("*Marzo*") in view of U.S. Patent No. 6,552,031 to Burch et al. ("*Burch*"). Claims 14-16 and 18-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Di Marzo* in view of *Burch* and further in view of WO 94/28913 to Kyle et al. ("*Kyle*"). In response to the Decision, Applicants have amended the claims to distinguish over the cited references as set forth below.

Independent Claims 1 and 14-16 have been amended to recite, in part, an orally administrable composition comprising a steroidal or non-steroidal anti-inflammatory drug ("NSAID"), a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament, and an inhibitor of an anandamide inactivating enzyme (amidase). The inhibitor can be, for example, oleate, oleamide, palmitate, palmitoylethanolamide, linoleylethanolamide, 2 palmitoylglycerol or 2-linoleylglycerol.

The combination of the naturally occurring precursor and a typical steroid or non-steroidal anti-inflammatory drug ("NSAID") provides a synergy advantage that occurs because the combination has the ability to diminish inflammatory via different pathways. In addition, the particular effect arising from a combination of the precursor and the amidase inhibitor (i.e., the effect of a compound having anandamide like activity as well as its inhibited breakdown) provides the advantage that the anandamide activity of the metabolite formed endogenously is

potentiated by both inhibiting the breakdown of a metabolite having anandamide-like activity and by the saturated N-arachidonylethanolamine compound binding to the CB2 receptor. The mixture of the precursor/amidase inhibitor, e.g., in the form of a triacyclgylcerol, further provides the following advantages: (i) merely one compound (instead of two) has to be added to the composition facilitating its preparation in terms of solubility/mixability, (ii) the amidase inhibitor is presented in close spatial relationship with the actual substrate - the precursor - to the respective converting enzymes with the consequence that the amidase will be inhibited to a higher extent, and (iii) all constituents, i.e., glycerol, precursor and amidase inhibitor, are generally considered safe fulfilling nutritional standards that assist in manufacturing and approval procedures.

The cited references alone or in combination fail to disclose or suggest a single orally administrable composition containing a steroidal or non-steroidal anti-inflammatory drug ("NSAID"), a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament, and an inhibitor of an anandamide inactivating enzyme (amidase) as required by amended independent Claims 1 and 14-16. Moreover, the cited references fail to teach or even suggest the synergistic advantages and benefits of the orally administrable composition including at least the three claimed components in a single composition.

Marzo is alleged to disclose that 2-arachidonoyl-glycerol has cannabimimetic activity. *Burch* discloses a pharmaceutical composition comprising a combination of a dose of rofecoxib or a pharmaceutically acceptable salt thereof and a dose of oxcodone or a pharmaceutically acceptable salt thereof in an amount sufficient to provide an analgesic effect in a human patient. Nevertheless, *Marzo* and *Burch* do not disclose orally administrable compositions in accordance with the present claims. In addition, *Marzo* and *Burch* fail to disclose or suggest that their compositions further include an inhibitor of an anandamide inactivating enzyme (amidase).

Kyle discloses a method of treating neurological disorders, including certain neurodegenerative diseases and psychiatric disorders, by administering a composition comprising a therapeutically effective amount of a single cell microbial oil comprising docosahexaenoic acid ("DHA"), a single cell oil comprising arachidonic acid ("ARA") or a combination of DHA- and ARA-containing oils, to a person in need of such treatment.

However, *Kyle* fails to disclose or suggest an inhibitor of an anandamide inactivating enzyme (amidase) anywhere in his disclosure.

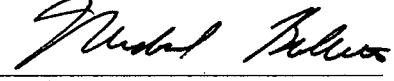
For at least the reasons discussed above, the cited references fail to disclose or suggest each and every element of amended independent Claims 1 and 14-16. As a result, Applicants respectfully submit that independent Claims 1 and 14-16, along with any of the claims that depend from Claims 1 and 14-16, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to the pending claims be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

K&L GATES LLP

BY 

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